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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,870	10/12/2001	David Mark Whitcombe	1991-211	8792
6449	7590	01/09/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/974,870

Applicant(s)

WHITCOMBE ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 101-11, 13-22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The amendment filed 9/26/2003 has been entered. Following the entry of the amendment filed 7/7/2003, the claims 10-11, 13-22 and 24 are pending.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 10-11 and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcombe et al. (WO 97/42345).

Whitcombe et al. disclose a diagnostic primer having a non-complementary tail comprising tag and detector region (See the Abstract and pg. 2, lines 1-10). The non-complementary tail is non-complementary to any relevant genomic sequence or adjacent region (See pg. 3, lines 26-27). The length of the primer is less than 200 base pairs (See pg. 24). The detector region may be detected by the use of fluorescence resonance energy transfer or measuring a change in fluorescence polarization (See pg. 2, lines 27-31). A solid phase probe is to detect the immobilized primer extension products (See pg. 3, lines 1-3). The primer also comprises a restriction site on the middle position of the primer which may be cleaved releasing the detected fluorophore from its quencher (See pg. 15, lines 12-13).

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The claim language does not structurally specify the differences between the phrases "a template binding region", "target binding region" and "linker". The claim language also does not limit what is "a self-complementary stem duplex". In a nucleic acid sequence, complementary base pair region would satisfy the limitation of self-complementary stem duplex. Furthermore, the claim language does not limit what are the regions of internal hybridization that stabilize one or more component(s) of the signaling system in a given position. Thus, basis upon the analysis above, the teachings of Whitcombe et al. anticipate the limitations of claims 10-11 and 14-22.

Applicant's arguments filed 9/26/2003 have been fully considered but they are not persuasive. The response argues that Whitcombe reference does not teach or suggest the primers as defined in amended claims 10-11, nor does it teach or suggest primers which allow for the interactions defined in those claims and a key feature of the primers of the present invention is that the tail of the primer remains uncopied. However, claims 10-11 and 14-22 are drawn to a diagnostic primer comprising a template binding region and a tail comprising a linker and a target binding region. The features of the primer used in the method of Whitcombe et al. satisfy the physical and functional features of the diagnostic primer of the instant invention. The response's argument are drawn to the intended use of the primer and do not sufficiently impart a limitation that distinguishes it from the teachings of Whitecombe et al.. Thus, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcombe et al. (WO 97/42345) as applied to claims 10-11 and 14-22 above, and further in view of Mullis et al. (4,800,159).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The teachings of Whitcombe et al. are set forth in section 1 above.

Whitcombe et al. do not disclose that the primer has blocking moiety and the kit containing the primer.

Mullis et al. disclose that an oligonucleotide has blocking moiety which is deoxyribonucleotide or ribonucleotides (See column 6, lines 12-19). Mullis et al. also disclose a kit comprising primers (See column 3, lines 24-46).

One of ordinary skill in the art at the time of instant invention would have been motivated to make a primer comprising a blocking moiety and a kit comprising primers as taught by Mullis et al. because Mullis et al. address blocking moiety which is deoxyribonucleotide or ribonucleotides used in a primer or oligonucleotide and that the using of block moiety in the

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primer depends on the ultimate function or use of the oligonucleotide (See column 6, lines 12-19). Moreover, constructing a kit comprising primer for certain usage was well known and commonly practice in the art for the convenience of performing a method. Thus, it would have been prima facie obvious for an ordinary skill in the art to make the kit comprising primers and constructing primer with blocking moiety in the tail.

Applicant's arguments filed 9/26/2003 have been fully considered but they are not persuasive. The response argues that Whitcombe teaches away from the primers of the present invention and Mullis et al.'s reference does not compensate for the deficiencies of the Whitcombe reference. As discussed in section 1 above, the features of the primer used in the method of Whitcombe et al. satisfy the limitations of the diagnostic primer of the instant invention. Based upon the analysis of the Office action mailed 3/26/2003, restating above, Mullis et al. address blocking moiety which is deoxyribonucleotide or ribonucleotides used in a primer or oligonucleotide and that the using of block moiety in the primer depends on the ultimate function or use of the oligonucleotide (See column 6, lines 12-19). Thus, it would have been prima facie obvious for an ordinary skill in the art to make the kit comprising primers and constructing primer with blocking moiety in the tail. Thus, the rejection is maintained.

#### ***Summary***

7. No claims are allowable.

#### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37-CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action..

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9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112 (the new telephone number, (571) 272-0790 after 1/22/2004). The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung  
December 17, 2003

*Jeffrey Siew*  
JEFFREY SIEW  
PRIMARY EXAMINER

*1/7/04*